

57. (New) The composition of claim 45, wherein the vitamin component is a mixture of retinyl propionate, Vitamin D3 and (dl) alpha tocopheryl acetate.

REMARKS

Claims 1- 43 stand rejected. In the present Amendment, claims 1, 5, 13, 20, 23, 24, 31, 33, 42 and 43 have been amended. New claims 44 - 57 have been added. No new matter has been introduced into the present application by the amendments to the claims or by the addition of the new claims. Reconsideration of the present application is respectfully requested in view of the following remarks.

Applicants have determined that the set of claims that were filed in this application does not include a claim 28. Accordingly, it is respectfully submitted that claims 29-57 will have to be renumbered at some point in the prosecution. It is respectfully requested that the renumbering of claims 29-57 be held in abeyance until there is an indication of allowable subject matter in the claims of the present application.

The rejection of claims 1-41 under 35 U.S.C. 112, first paragraph is respectfully traversed for the reasons set forth below.

Initially, it is respectfully submitted that the reasoning provided for this rejection does not apply to claims 17 and 37. With respect to the other claims cited in the rejection, it is respectfully submitted that an artisan of ordinary skill, after reading and understanding the specification of the present application, would know how to prepare a liquid vitamin composition of the present

invention using one or more precursors of Vitamin A or Vitamin E as recited in the claims.

Although it is possible that the artisan might have to perform a minimal amount of experimentation to make sure that each component in the composition is compatible with all of the other components in that particular composition, such experimentation is not excessive and is the standard procedure in this art for preparing liquid vitamin compositions. The law is well settled that a lack of enablement rejection cannot be based on the possibility that an artisan would have to perform routine experimentation in order to achieve the claimed invention, as long as the experimentation is not excessive. In the present situation, an artisan can choose from the precursors of Vitamin A and Vitamin E that are known at the time he wishes to prepare a liquid vitamin composition according to the claims and combine them in amounts that fall within the range specified in the present claims. If the precursors are not compatible and/or do not form the desired vitamin(s) in-vivo, then the artisan has not prepared a liquid vitamin composition according to the present claims. However, it is incorrect to say that the artisan is not enabled by the teachings of the present application simply because certain precursors may be incompatible with the other components of the composition or may fail to form the desired vitamins in-vivo. By reading and understanding the present application, the artisan knows what he wants to produce and how to produce it, all that is left is to prepare a particular composition and make sure that all of its ingredients are compatible and that the precursors convert to the desired vitamin in a satisfactory manner in-vivo. Since these testing procedures are routine and well known to those of ordinary skill in the art, there is no need for applicants to provide an extensive list of possible

precursors or a large number of working examples demonstrating alternate formulations. The written description and working examples provided in the present application are more than enough to enable an artisan of ordinary skill to successfully practice the invention of the present claims.

In view of the above, it is respectfully submitted that the specification of the present application meets all of the requirements of 35 U.S.C. 112, first paragraph.

The rejection of claims 5, 13, 24, 42 and 43 under 35 U.S.C. 112, second paragraph, is respectfully traversed. However, it is respectfully submitted that this rejection has been rendered moot by the amendments to the claims.

It is respectfully submitted that the amendments to the claims were not made to overcome any prior art. Further, none of the amendments were intended to further limit the scope of the claims or to disclaim any subject matter. All of the amendments to the claims were made to use claim language that was more desirable to the Examiner. Accordingly, it is respectfully submitted that by making the amendments to the claims, applicants did not intend to limit the scope of equivalents that would normally be available to the elements of the claims that were amended. For example, by deleting the word "substantially" from claims 5 and 24, applicants did not intend that those claims should be strictly limited to compositions that contain none of the recited alcohols. Instead, applicants intend that these claims should be read as being limited to compositions that do not contain enough alcohol to affect the properties of the composition (for example, by lowering the flashpoint of the composition to below about 200°C).

With respect to claims 1, 20, 23, 31, 42 and 43, it is respectfully submitted that the amendments to these claims do not narrow the scope of the claims. The same is true of the amendments to claims 13 and 33, wherein the definition of "adequately disperses" that was used in the specification was substituted for the phrase "adequately disperses" in the claims.

The rejection of claims 1- 43 under 35 U.S.C. 103(a) as being unpatentable over M.V.I.-12 package insert in view of Multi-12 package insert, the Merck Index and Lundberg is respectfully traversed for the reasons set forth below.

Initially, it is respectfully submitted that the dates printed on the two package inserts are not sufficient to establish that these documents are actually prior art to the present application. There is no proof that the package inserts were ever used or made public in any way. Without such proof, these inserts cannot be used as prior art against the present application.

The following remarks are being made with the assumption that the Examiner will be able to prove that the package inserts are actually prior art to the present application. If the Examiner cannot supply such proof, the following remarks are unnecessary.

The rejection under 35 U.S.C. 103(a) is deficient for at least the following reasons.

- (1) The Examiner has not provided a reasonable explanation of why an artisan of ordinary skill would be motivated to combine the teachings of the two package inserts by employing Vitamin D3 oil in the composition described in the M.V.I.-12 insert.
- (2) The Examiner has not provided a reasonable explanation of why an artisan of ordinary skill would be motivated to combine the teachings of the two package inserts, the Merck Index and Lundberg by employing a C4 to C6 alkyl lactate and ethoxyquin in the composition described in the M.V.I.-12 insert.

- (3) The Examiner has improperly used the teachings of the present application as part of his rationale for the obviousness rejection.

With respect to (1), the Examiner has correctly noted that the M.V.I.-12 package insert, *not required* does not disclose or suggest a composition that contains Vitamin D3. Further, as the Examiner *locally in re* stated earlier in the Office Action, vitamin compositions are known to be unstable and, therefore, one cannot assume that a given composition will remain stable if an additional ingredient is added to it. Accordingly, an artisan of ordinary skill would not be motivated to simply add Vitamin D3 to the composition of M.V.I.-12 without some teaching or suggestion that the new composition would be stable and that there would be some advantage to adding Vitamin D3. The compositions of M.V.I.-12 and Multi-12 are not the same, so there is no teaching or suggestion provided by the Multi-12 insert that the new composition would be stable. Further, since there is no teaching in the Multi-12 insert that the use of Vitamin D3 is especially beneficial or advantageous, there is no reason why an artisan would be motivated to add Vitamin D3 to the M.V.I.-12 composition. *hindering* It is respectfully submitted that the Examiner has used the composition of the present claims as a template and has then proceeded to select the various components of the composition from multiple documents that are not properly combinable absent the motivation that is provided by reading the specification and claims of the present patent application.

With respect to (2), the Examiner has cited Lundberg as teaching that butyl lactate is a solvent for oils and can be used in food products and the Merck Index as teaching that ethoxyquin is a known antioxidant for use in food products. It is the Examiner's position that it is prima

facie obvious to substitute a known solubilizer with another solubilizer and a known antioxidant with another antioxidant. Applicants do not dispute this point. However, with respect to the butyl lactate portion of the Examiner's position, applicants are not simply substituting a known solubilizer with another solubilizer. The C4 to C6 alkyl lactate component of the composition of present claims 1 to 19, 40, 42, 44, 45, 46, 47, 49, 50, 52, 53, 55 and 56 is used in addition to other known solubilizers, such as polysorbate 80, which fall under the "emulsifiers" element of these claims. There is no teaching or suggestion in any of the cited references that it would be beneficial or advantageous to use a C4 to C6 alkyl lactate component in addition to other known solubilizers. Accordingly, the above-identified claims cannot be said to be obvious over the documents cited by the Examiner.

In addition, there is no explanation in the Office Action as to why this rejection is relevant to claims 20 - 39, 41, 43, 45, 48, 51, 54 and 57, which claim the use of a C1 to C3 alkyl lactate instead of a C4 to C6 alkyl lactate.

With respect to (3), although the Examiner has acknowledged that the cited documents do not contain any teachings with respect to the flashpoint temperature, water dispersion time or viscosity of the compositions they disclose, the Examiner has taken the position that one of ordinary skill would have been motivated to employ the percentage ranges of weights and ratios of actives and excipients that are set forth in applicants' claims to "obtain the recited flashpoint temperature, water dispersion time, and composition viscosity". This argument is a classic case of hindsight reconstruction. If the cited documents do not contain any teachings concerning the

properties recited in the claims of the present application, why would an artisan modify the composition and amounts of the various components in order to achieve those properties? It is impermissible to use the teachings of the application under examination as part of the basis for an obviousness rejection. The motivation to combine the prior art and the motivation to modify the compositions and amounts of the various components in the prior art must come solely from the prior art itself. The teachings of the present application cannot be used as a basis for the motivation to combine or modify the prior art to arrive at the invention of the present claims. However, in the present situation, that is exactly what the Examiner has done.

Accordingly, for the reasons set forth above, it is respectfully submitted that the rejection under 35 U.S.C. 103(a) is incorrect and should be withdrawn.

In addition to the above, it is also respectfully submitted that the invention of the present claims is not obtained even if the documents cited by the Examiner are combined in the manner suggested by the Examiner. Specifically, all of the claims of the present application call for at least 2% by weight of the C1 to C3 or C4 to C6 alkyl lactate component in addition to at least 20% of the emulsifier component (which is equivalent to the "solubilizers" the Examiner referred to in the Office Action). In accordance with the Examiner's reasoning, this means that the compositions of the present claims contain at least 22% by weight of "solubilizers". In contrast, the M.V.I.-12 composition contains only 1.6% by weight of polysorbate 80 and the Multi-12 composition contains only 1.4% polysorbate 80. Therefore, even if an artisan of ordinary skill were to somehow find the motivation to combine the documents cited by the Examiner in the

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manner proposed by the Examiner, that artisan would not obtain the composition of the present claims because, among other differences, the composition obtained would contain less than 2% of "solubilizers".

Reconsideration of the present application and a favorable action concerning claims 1-27 and 29-57 is respectfully requested.

Respectfully submitted,
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Enclosure: Appendix A - Marked-up Version of Amended Claims
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Appendix A
Marked-Up Version of Amended Claims

1. (Amended) A water-dispersible [and substantially non-combustible] liquid vitamin composition comprising:

a) from 10% to 60% by weight of a vitamin component selected from the group consisting of:

(i) one or more precursors of Vitamin A;

(ii) one or more precursors of Vitamin E;

(iii) a mixture of one or more precursors of Vitamin A and one or more precursors of Vitamin E;

(iv) a mixture of one or more precursors of Vitamin A and Vitamin D3;

(v) a mixture of one or more precursors of Vitamin E and Vitamin D3; and

(vi) a mixture of one or more precursors of Vitamin A, one or more precursors of Vitamin E, and Vitamin D3;

b) from 2% to 15% by weight of a C4 to C6 alkyl lactate;

c) from 20% to 50% by weight of one or more veterinarily acceptable emulsifiers;

d) from 1% to 15% by weight of water; and

e) from 2% to 10% of an oil;

wherein the flashpoint of the composition is about 200°F or greater.

5. (Amended) The composition of claim 1, wherein the composition is [substantially] free of a flammable alcohol.

13. (Amended) The composition of claim 1, wherein said composition [adequately] disperses into water and forms a finely divided emulsion within 2 minutes when added at a ratio of composition to water of from 1 g/kg to 50 g/kg and stirred manually at a temperature of from 15°C to 25°C.

20. (Amended) A water-dispersible [and substantially non-combustible] liquid vitamin composition comprising:

a) from 10% to 60% by weight of a vitamin component selected from the group consisting of:

- (i) one or more precursors of Vitamin A;
- (ii) one or more precursors of Vitamin E;
- (iii) a mixture of one or more precursors of Vitamin A and one or more precursors of Vitamin E;
- (iv) a mixture of one or more precursors of Vitamin A and Vitamin D3;
- (v) a mixture of one or more precursors of Vitamin E and Vitamin D3; and
- (vi) a mixture of one or more precursors of Vitamin A, one or more precursors of Vitamin E, and Vitamin D3;

b) from 3% to 15% by weight of a C1 to C3 alkyl lactate;

c) from 20% to 50% by weight of one or more veterinarily acceptable emulsifiers;

d) from 3% to 15% by weight of water; and

e) from 2% to 10% of an oil;

wherein the flashpoint of the composition is about 200°F or greater.

23. (Amended) The composition of claim [24] 20, wherein the amount of the C1-C3 alkyl lactate is from 3% to 12%.

24. (Amended) The composition of claim 20, wherein the composition is [substantially] free of a mono-hydroxy alcohol.

31. (Amended) The composition of claim [22] 20, wherein the viscosity of the composition is from 1000 cP to 10000 cP at 0°C.

33. (Amended) The composition of claim 20, wherein said composition [adequately] disperses into water and forms a finely dispersed emulsion within 2 minutes when added at a ratio of composition to water of from 1 g/kg to 50 g/kg and stirred manually at a temperature of from 15°C to 25°C.

42. (Amended) A water-dispersible [and substantially non-combustible] liquid vitamin composition comprising:

- a) from 1% to 6% by weight of Vitamin D3;
- b) from 2% to 15% by weight of a C4 to C6 alkyl lactate;
- c) from 20% to 50% by weight of one or more veterinarily acceptable emulsifiers;
- d) from 1% to 15% by weight of water; and
- e) from 5% to 30% by weight of an oil;

wherein the flashpoint of the composition is about 200°F or greater.

43. (Amended) A water-dispersible [and substantially non-combustible] liquid vitamin composition comprising:

- a) from 1% to 6% by weight of Vitamin D3;
- b) from 3% to 15% by weight of a C1 to C3 alkyl lactate;
- c) from 20% to 50% by weight of one or more veterinarily acceptable emulsifiers;
- d) from 1% to 15% by weight of water; and
- e) from 5% to 30% by weight of an oil;

wherein the flashpoint of the composition is about 200°F or greater.